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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,436	10/27/2003	Kathleen C.M. Campbell	STU 7397	8942

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,436	CAMPBELL, KATHLEEN C.M.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-20,23-32 and 38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-20,23-32 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/09 has been entered.

2. Applicant's arguments filed 4/27/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 4-20, 23-32 and 38-40 are pending in this office action.

5. The rejection of claims 1, 7-9, 20 and 23-25 under 35 U.S.C. 102(b) as being anticipated by Gabrilove (US 4,961,926) is withdrawn because Gabrilove fails to teach the claimed compound D-methionine and/or L-methionine as required by the claims.

6. Claims 1, 6-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammes et al. (US 3,652,290).

Hammes teaches administering a composition of vitamin C and D, L-methionine (see abstract, as it relates to claims 1 and 6). Even though Hammes did not explicitly teach administration for reducing oral mucositis in patients exposed to radiation, it is noted that humans are exposed to radiation everyday, such as UV light and radon. Therefore once the formulation of Hammes is taken orally, it will inherently reduce oral mucositis both prior, simultaneously and subsequently (i.e., as it relates to claims 7-12). It should also be noted that there is no other distinguishing step is recited. All that is required for the method is the administration of the active agent.

Hammes also teaches D,L methionine is administered at 3% of vitamin C which equates to 0.0205 mg/ml. An average beverage drink is 0.5L which then equals to 10 mg. An average human weighs 70Kg x 10 is 700 mg (as required by instant claim 13-15). It should be noted that administering a supplemental amount of methionine, orally would reasonably achieve the serum levels equivalent to those achieved via parenterally doses from 1.0 mg-500 mg/kg body weight as calculated above, because the same compound is administered.

7. Claims 1, 4-9, 10-19 and 26-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell (US 6,187,817) in view of Gabrilove, (US 4,961,926) further in view of Kil et al., (WO 03/045334) for the reasons made of record in Paper No. 20081208 and as follows.

Applicant argues several separate grounds for finding obviousness under KSR.

In response careful consideration has been given to the seven factors argued regarding KSR, however this is found not persuasive because it is well known in the art that oral mucositis is a result of treatment from chemotherapy and radiotherapy. It is well known in the art that gastrointestinal toxicity is most visible in the mouth and is a result of chemotherapy. See evidence presented by Eting et al. pages 1202, 4th para. Therefore one skilled in the art would reasonably treat oral mucositis with the same active agent used in treating gastrointestinal toxicity. Thus substituting Gabrilove's compound with Campbell is reasonable since there is an overlap in the disease treatment. Campbell teaches reducing gastrointestinal toxicity by administering D-methionine, as required by instant claims 3-4 and 22 (see abstract and col. 1, lines 20). Gabrilove is introduced for the treatment of oral mucositis resulting from radiation.

It should again be noted, as discussed in the last office action, all that the claims require is that methionine is administered. It is noted that Campbell does not expressly teach reducing oral mucositis, however, Campbell does teach administering D-methionine (i.e., a protective agent) to reduce or ameliorate toxic side effects of anticancer chemotherapeutic drugs (as it relates to instant claim 20). All that is required by the instant claim is the administration of the drug methionine.

8. Claims 38-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell (US 6,187,817) in view of Gabrilove (US 4,961,926) and further in view of Kil

et al. (WO 03/045334) as applied to claims 1, 4-9, 10-19 and 26-32 above for the reasons made of record in Paper No. 20081208 and as follows.

The above remarks and response are applied here.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20 and 23-32 are rejected on the ground of nonstatutory double patenting over claims 1, 3-5 and 7-32 of copending Application No. 10694448 (now a US pending Patent).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to treating diseases (reducing oral mucositis in the instant claims and reducing the incidence of ototoxicity in '448) in a patient undergoing treatment with a chemotherapeutic effective amount of an antitumor platinum coordination compound. Since there is no defining step other than administering methionine for the treatment of conditions related to the use of chemotherapeutic effective amounts of an antitumor platinum coordination compound, one of ordinary skill in the art would reasonably expect the different conditions to also be treated in a population experiencing the effects of the same antitumor platinum coordination compound.

10. Claims 20 and 23-32 are rejected under the judicially created doctrine of obviousness- type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,187,817.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to treating diseases (reducing oral mucositis in the instant claims and reducing ototoxicity in '817) in a patient undergoing treatment with a chemotherapeutic effective amount of an antitumor platinum coordination compound. Since there is no defining step other than administering methionine for the treatment of conditions related to the adverse effects of the same antitumor platinum coordination compound, one of ordinary skill in the art would reasonably expect these different conditions resulting from the effects of the same antitumor platinum coordination compound to also be treated.

11. Claims 1, 4-19 and 38-40 are rejected under the judicially created doctrine of obviousness- type double patenting as being unpatentable over claims 1-9, 11-13,15-25 and 27-33 of U.S. application No. 10/694,432.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to treating diseases resulting from exposure to radiation (such as reducing oral mucositis in the instant claims and treating alopecia in '432). Since there is no defining step other than administering methionine, one of ordinary skill in the art would reasonably expect administration of methionine to treat any condition related to the adverse effects of radiation.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618

/Robert C. Hayes/
Primary Examiner, Art Unit 1649